

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. Kent Croon
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
Chesterfield, Missouri 63198

SEP 25 1996

Dear Dr. Croon:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation event MON810. According to Monsanto, the new corn variety has been modified for resistance to the European Corn Borer through expression of the *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*.

Monsanto submitted a summary assessment of corn containing transformation event MON810 on June 6, 1996. This communication informed FDA of the steps taken by Monsanto to ensure that the product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0034. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented, we have no further questions concerning corn grain or fodder containing transformation event MON810 at this time. However, as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247 HFS-13
HFV-151 HFV-200 HFV-221 HEV-226 BNF0034